

Version Number: 1	Research & Development Policy 151-18	Supersedes Document Dated: N/A
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I. PURPOSE

The purpose of this Standard Operating Procedure is to document the process for Syracuse VA Medical Center review of human subject protocols being reviewed by the VA Central IRB (CIRB) as the IRB of record.

II. POLICY

- A. The VA CIRB has been established to provide review of multi-site VA-sponsored projects, is staffed by the Office of Research and Development (ORD) Program for Research Integrity Development and Education (PRIDE), and comprised of members throughout the country.
- B. The VA CIRB and Syracuse VAMC are both signatory institutions in this endeavor, who agree to abide by "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" as set forth in the Belmont Report (April 1979); share responsibilities for evaluation and management of conflict of interest in accordance with respective policies and standard operating procedures (SOPs); adhere to federal, VHA, DHHS, FDA and state guidelines regarding review of human subject research; and comply with the research use and disclosure of protected health information (PHI), in accordance with the Health Insurance Portability and Accountability Act (HIPAA). Both the VA CIRB and the Syracuse VAMC are responsible for maintaining current Federalwide Assurances through the Office of Research Oversight (ORO) and maintaining accreditation of their Human Research Protection Programs (HRPPs).
- C. A Memorandum of Understanding (MOU) is in place between the Syracuse VAMC and the VHA Central Office CIRB for the initial and continuing protocol review, as well as review of amendments, monitoring, reporting, and other relevant requirements, for select VA-funded, multi-site research projects involving human subjects. All applicable Syracuse VAMC R&D SOPs will apply to protocols using the CIRB, with this SOP providing the applicable exceptions to the Syracuse VAMC R&D SOPs.
- D. VA facilities that utilize the VA CIRB are accountable for local site investigator oversight and local Research and Development Committee (R&DC) approval. The local site is required to: 1) provide timely communication between the VA CIRB and the Principal Investigator/Study Chair or a Local Site Investigator during the initial review application process, 2) facilitate a smooth interface with local committees and subcommittees and any other non-IRB review entities, 3) maintain documentation of

training and credentialing of research team members, 4) monitor and audit projects, 5) report adverse events and unanticipated problems involving risks, 6) facilitate communication between the VA CIRB, the Principal Investigator/Study Chair and/or the Local Site Investigator and the facility during the post-study approval period, and 7) notify the VA CIRB of any non-compliance with any VA CIRB determinations and/or with local facility policies and procedures and ethical codes of conduct.

III. PROCEDURES

1. Principal Investigator of the multi-site study submits an application package for review by VA CIRB. The Syracuse VAMC investigator submits the Local Site Investigator Application package via the ACOS for Research to the VA CIRB for review.
2. Once the Principal Investigator and Local Site Investigator applications are reviewed at VA CIRB, the local investigator is notified of stipulations that must be addressed for VA CIRB approval. This process includes ensuring that the local site consent form and other documents reflect local site criteria. The local site investigator has 30 calendar days to address initial review stipulations. This response will be sent to the VA CIRB for further review.
3. Once the local site investigator receives official approval from the VA CIRB, Syracuse VAMC has 10 calendar days to determine whether it wishes to be a local study site. This determination is made by a review of the VA CIRB submission by the ACOS/R&D.
4. If the ACOS/R&D has any concerns about the study, or would like changes made to any study documents, the local R&D Committee Chair/designated members will be consulted and the Local Site Liaison (individual identified in the Memorandum of Understanding between the CIRB and the VA Medical Center) will convey these concerns to the local site investigator and the VA CIRB study-specific Coordinator.
5. After the ACOS/R&D reviews the submission, if it is determined that Syracuse VAMC will not be a local site, the local site investigator and the VA CIRB are notified.
6. After the ACOS/R&D reviews the submission, if it is determined Syracuse VAMC will be a local site, the following required materials will be forwarded to the R&D Committee for review: the Local Site Investigator Application package, the study abstract, VA CIRB approval documents, and other related study documents as needed. The R&D Chair or member designee will provide the R&D Committee with the overview of the study.
7. The local site submission is placed on the agenda for the next scheduled R&D Committee meeting.

8. Once the R&D Committee approves the study, the official notification of approval will be signed by the ACOS/R&D and sent by the local site liaison to the local site investigator and the VA CIRB study-specific Coordinator.

Note: The study cannot start until the PI has received the approval letter from both the VA CIRB and Syracuse VAMC's R&D Committee signed by the ACOS/R&D.

9. Continuing review of the study will be conducted by the VA CIRB, not the Syracuse VAMC IRB. However, the Local Site Liaison will forward the VA CIRB continuing approval to the R&D Committee for concurrence.
10. Protocol amendments will be administered via the VA CIRB Coordinator. The Local Site Liaison will forward the VA CIRB amendment approval to the R&D Committee for concurrence.
10. Local oversight to ensure compliance with all federal and VA regulations will include 100% informed consent audits annually and, at minimum, a triennial regulatory audit. In addition, audits conducted by the local facility Research Compliance Officer must also be forwarded to the VA Central IRB for review. These include the routine yearly informed consent audits and the tri-annual regulatory audits. The routine audits can be forwarded with the continuing review report if there are no issues (e.g., noncompliance that may be serious or continuing) that need to be brought to the attention of the VA Central IRB prior to continuing review. All other audit reports should be forwarded as they are completed and/or received.
11. All reports of non-compliance will be forwarded to the VA CIRB for resolution. The Local Site Liaison will also report all findings of non-compliance to the Syracuse VAMC R&D Committee. All instances of serious or continuing non-compliance will be reported as specified by VHA Handbook 1058.01.
 - a. VA CIRB and Syracuse VAMC's Research personnel will have access to the research subjects' clinical records and/or case files for oversight and monitoring.
12. It is the local site investigator's responsibility to report all complaints, unanticipated problems involving risks to subjects or others related to the research, serious adverse events, suspension and/or termination of research, research impropriety, misconduct or restriction of any research team member to the VA CIRB and to the Syracuse VAMC R&D Committee.
13. Syracuse VAMC will be communicated to the VA CIRB by the Syracuse VAMC's Local Site Liaison.
14. All suspensions or termination by Syracuse VAMC's R&D Committee or by the Syracuse VAMC Facility Director will be communicated to the VA CIRB.

15. Syracuse VAMC will maintain documentation that all required training, credentialing and privileging is up to date for the local site PI and research staff of VA CIRB approved projects.

16. Investigator Responsibilities:

- a. Reporting problems per #11 above.
- b. The investigator will not independently modify any VA CIRB-approved study except where necessary to eliminate apparent immediate hazards to subjects. The investigator must notify the VA CIRB within 5 working days if such an action is taken.
- c. VA CIRB will not review emergency use of test articles. All emergency use drugs or devices are reviewed according to Syracuse VAMC's emergency use policy.
- d. Comply with all state, local or Syracuse VAMC requirements related to the protection of human subjects.
- e. Report all additions and removals of research team members to the VA CIRB and the Syracuse VAMC R&D Committee.
- f. Coordinate all Syracuse VAMC subcommittee approvals as required, e.g., radiation safety, SRS. Copies of subcommittee approvals must be submitted to the VA CIRB.
- g. Comply with all VA CIRB standard operating procedures (SOPs) as applicable. VA Central IRB SOPs can be found at:
<http://www.research.va.gov/programs/pride/cirb/forms/default.cfm>

IV. REFERENCES

VA CIRB and Syracuse VAMC MOU, executed May 4, 2009
VA CIRB Webpage/Forms
VHA Handbook 1200.5
VHA Handbook 1200.01
Syracuse VAMC R&D SOP 151-01 "Research and Development Committee"

V. RESCISSION

None


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